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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,679	05/29/2007	**Gavril W. Pasternak**	62078(51590)	5097

21874 7590 07/25/2008

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
07/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,679	PASTERNAK ET AL.	
	Examiner	Art Unit	
	ROBERT LANDSMAN	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☒ Claim(s) *1-6* is/are allowed.

6)☒ Claim(s) *7 and 14-20* is/are rejected.

7)☒ Claim(s) *8-13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Response filed 6/2/08 to the Restriction Requirement mailed 3/31/08 has been entered into the record.

B. Claims 1-21 are pending. Group I, claims 1-20, are the subject of this Office Action as discussed below in the Answer to the Traversal.

2. Answer to the Traversal

A. In the Response filed 6/2/08 Applicants provisionally elect Group I, claims 1-20. However, Applicants argue that SEQ ID NOs 51, 53, 55, 57, 59 and 61 are all splice variants of the mu opioid receptor and that the art cited by the Examiner fails to teach or suggest the instantly claimed sequences. These arguments have been considered and are deemed persuasive. However, claim 21, drawn to a separate method of using the polypeptides of the invention, remains withdrawn as a separate invention. However, the following applies –

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Therefore, the Restriction between Groups I and II has been withdrawn. However, the Restriction between Groups I/II and III remains. This Restriction is deemed proper and is made FINAL.

3. Specification

A. The specification is objected to since Figure 1A not labeled as such in order to match the Brief Description of the Figures.

B. Though none could be found, Applicant is advised that embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference.

C. Though none could be found, trademarks should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

D. Though none could be found, any U.S. or Foreign Applications cited in the specification which have since issued should be updated with the corresponding Patent No.

4. Claim Objections

A. Claim 7 is objected to. It is suggested that the phrase "The polypeptide selected" be amended to "A polypeptide selected" and "in which the polypeptide" be replaced with "wherein said polypeptide".

B. Claims 8-13 are objected to. The term "antisense" raises potential issues under 35 USC 112, first paragraph, with regard to enablement. However, since the claims are limited to only those "antisense"

molecules that are "fully complementary" then it is suggested that the term "antisense" be replaced with, e.g., "a fully complementary polynucleotide" "or the full complement thereto".

5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 14-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening compositions where both the control and test cells are the same cell line, does not reasonably provide enablement for a method of screening wherein the cell lines are different. Furthermore, while being enabling for the screening of GTPgS in CHO cells (as seen in the Examples), it does not provide enablement for screening assays which are able to detect the neuroendocrine hormones of claims 17 and 18 using the cells (e.g. CHO) taught in the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification only provides guidance and working examples as to the use of using the same cell line for both the control and test. However, claim 14 is not limited to using the same cell line. It is not predictable to the artisan how to screen compounds using different cell lines for the control and for the test.

Furthermore, with regard to claims 17 and 18, Applicants have not provided any guidance or working examples of any assay, including cell lines, which can be used to screen for the claimed neuroendocrine hormones. The specification does teach that morphine does exert effects on many of the systems of these claims (page 3, lines 15-24); however, again, no in vitro model has been disclosed in the instant specification.

For these reasons, the Examiner has concluded that undue experimentation is required to practice the invention as claimed.

6. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 7 confusing since it is not clear how a polypeptide comprise a "composition".

B. Claim 19 is confusing since it is unclear in part (c) what the point is of control. No discussion of the control is ever discussed after part (c). Furthermore Part (e) is confusing since implies that the measurement is the binding of the composition and opioid are to each other instead of to the polypeptide.

7. Conclusion

A. Claims 1-6 are allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647